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XILAS MEDICAL, INC.

September 30, 2003

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is **K030829**.

1. **Submitter:**

   Xilas Medical Inc. (formerly Salix Medical, Inc.)
   12665 Silicon Drive
   San Antonio, Texas 78249

2. **Name of Device:**

   Vibration Perception Threshold (VPT) Meter

3. **Predicate Device Information:**

   The VPT Meter is similar to the following predicate device:
   1) Vibrameter, Somedic AB, Stockholm, Sweden (510(k) number K843486).

4. **Device Description:**

   The Xilas Medical VPT Meter is designed to identify patients with sensory neuropathy. These patients have lost sensation and the "gift of pain" from their extremities or elsewhere. The instrument provides a quantitative measurement of vibration perception threshold (VPT). The digital device allows the clinician to quantify the loss of sensation, initially to establish a baseline loss of sensation and subsequently monitor the progression of established pathology.

5. **Intended Use:**

   The VPT Meter is an instrument designed to measure simply and accurately the threshold of appreciation of vibration in human subjects.

12665 Silicon Dr. • San Antonio, TX 78249 • (210) 692-1114 • Fax (210) 692-1144
www.xilas.com

6. **Substantial Equivalence:**

The Xilas Medical VPT Meter is substantially equivalent to the Vibrameter, a product produced by Somedic AB, Stockholm, Sweden.

- Both devices consist of a control box and a handheld vibration apparatus. The handheld apparatus on both devices is similar in size, shape and weight and both use a tip to transfer vibrations to the patients skin.
- Both devices have a digital display and easy access to the control mechanism on the face of the box.
- Both devices are free standing and independent and do not require a computer interface to achieve the desired output.
- Both devices vibrate at a similar frequency and vibration displacement.
- Both devices ramp up power to the handheld vibration apparatus, which changes the amplitude of the vibration displacement at the tip.
- Both devices are dependent on patient acknowledgement of the level where vibration is being felt.
- The Vibrameter measures in microns and the VPT Meter measures in volts, however in the VPT Meter User's Manual a conversion graph is provided that represents the relationship between microns and volts.
- Both devices are easy-to-use and non-invasive.
- Both devices are designed to be used as a clinical assessment tool by health care professionals to evaluate peripheral sensory neuropathy on the upper and lower extremities.

7. **Conclusions:**

The Xilas Medical VPT Meter has the same intended use and similar characteristics to the Somedic AB Vibrameter. Testing of the device (included with this submission) demonstrates the VPT Meter to be both safe and efficacious. Therefore, the VPT Meter is substantially equivalent to the predicate product, the Vibrameter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 2003

Mr. Ruben G. Zamorano
President
Xilas Medical, Inc.
12665 Silicon Drive
San Antonio, Texas 78249

Re: K030829
Trade/Device Name: Vibration threshold measurement device
Regulatory Class: Unclassified
Product Code: LLN
Dated: September 30, 2003
Received: October 2, 2003

Dear Mr. Zamorano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K030829

Device Name: VPT Meter

Indications For Use:

The VPT Meter is an instrument designed to measure simply and accurately the threshold of appreciation of vibration in human subjects.

Prescription Use ___XX___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030829